## REMARKS

The Final Office Action mailed March 22, 2001, has been received and its contents carefully noted. In order to advance prosecution and gain entry of new method claims as a matter of right as discussed during a personal interview with the Examiner, Dr. Liliana Di Nola-Baron, and Primary Examiner, Dr. Gollamundi S. Kishore , conducted March 15, 2001, the Application was refiled as a Request For Continued Examination on September 21, 2001. Undersigned Counsel indicated on the Request For Continued Examination (RCE) Transmittal form that a Preliminary Amendment would follow shortly (see section 2 (b)). However, a Notice Of Improper Request For Continued Examination (RCE) dated October 25, 2001 (copy attached) was received, followed by a Notice of Abandonment dated November 5, 2001.

This Preliminary Amendment accompanies a Petition For Revival Of An Application For Patent Abandoned Unintentionally under 37 C.F.R. 1.137 (b) and amends claims 15, 17, 18, 24, 25, and 27, adds new claims 38 and 39 to the Application, and replaces the title with a new title which reflects the subject matter of the pending claims.

New claims 38 and 39 find support in the specification and in claims 15 and 22.

An additional claim fee of $ 168.00 for the addition of two independent in excess of three is due and an additional claim fee of $36.00 for two total claims in excess of 20 is now due, and a check covering this amount ($168.00 + $36.00 = $204.00) is attached. Should any additional claim fee be deemed due, please charge the same to Deposit Account No. 22-0261 and advised us accordingly.

**Claims 15-39 are now pending in the Application and are submitted to be in allowable condition for the reasons given in the following.**

Applicants thank the Examiner, Dr. Liliana Di Nola-Baron, and her supervisor, Primary Examiner, Dr. Gollamundi S. Kishore , for the courtesy shown Applicants' representative during the personal interview conducted March 15, 2001. During the interview, the references applied against the claims were discussed, arguments distinguishing the invention were presented, and proposed claim changes were discussed. While no agreement was reached, the Examiner's indicated that method claims, e.g., "A method of controlling dissolution time of a coating, ...", reciting detailed steps might be accorded more favorable treatment. New claims 38 and 39 are such method claims and are submitted to be in allowable condition.

**The rejection of claims 15, 17, 20, 22, 24, 27, 29, 30, 33, and 36 under 35 U.S.C. §102 as anticipated by Provonchee et al. (US 4,774,093) is respectfully traversed.**

Applicants do not agree that Provonchee et al. anticipate these claims because the disclosure of Provonchee et al. does not meet Applicants' new claims which recite, "... a coating agent **which is a plastic fluid**, ...[emphasis added]", (see the specification, page 14, line 8, "plastic fluid").

Provonchee et al. disclose a polysaccharide composition of the gel-forming beta-1,3-glucan type and methods of preparing and using said polysaccharide composition. The disclosure of Provonchee et al. teaches substances which are **pseudo-plastic fluids** as observed in general polymers. The present invention is distinguishable in that Applicants' coating agent is **a plastic fluid**, i.e., a non-Bingham body, such as ketchup (see the specification, page 14, line 8). This distinction is submitted to be well known in the art.

References:

| | | |
|---|---|---|
| (a) Newton fluid: | | water, oil, air |
| (b) non-Newton fluid: | Bingham fluid | asphalt, paint |
| | pseudo-plastic fluid | polymer solution, starch paste |
| | dilatant fluid | starch+water, mixture of water and sand |

Therefore, the coating agent of the present invention is submitted to be distinguishable and essentially different from the substances employed by Provonchee et al.

Additional distinguishing features include (1) - (4) which follow:

(1) The disclosure of Provonchee et al. teaches gel formability. The present invention is distinguishable in that gel formability is not observed and is not desired. Applicants' coating agent is **a plastic fluid**, i.e., a non-Bingham body, such as ketchup (see the specification, page 14, line 8).

(2) The disclosure of Provonchee et al. teaches substances which are normal chain polysaccharides, such as curdlan, which are soluble in an alkaline aqueous medium. The present invention is distinguishable in that Applicants' coating agent is not soluble in an alkaline aqueous medium.

(3) The disclosure of Provonchee et al. teaches substances which are pH dependent , namely, of the alkaline soluble type, so that release of pharmaceuticals encapsulated by the substances of Provonchee et al. require an alkaline medium. The present invention is distinguishable in that Applicants' coating agent is pH-independent and able to dissolve under preselected dissolution times (see the data presented in Applicants' Figure 2).

(4) The disclosure of Provonchee et al. teaches substances having oxygen permeability which can be surmised form the disclosed use for contact lenses which require oxygen permeability. The present invention is distinguishable in that Applicants' coating agent has oxygen barrier ability, i.e., the level of oxygen permeability is extremely low (see Applicants' specification page 28 and 29, Example 11).

**The rejection of claims 15, 17, 20, 22, 24, and 27 under 35 U.S.C. §102 as anticipated by Shank (US 4,001,408) is respectfully traversed.**

Applicants do not agree that Shank anticipates these claims because the disclosure of Shank does not meet Applicants' claims. The coating agent, coated material, and coating film of the present invention are distinguishable and essentially different from the substances employed and the coating result obtained by Shank for the reasons which follow.

Shank discloses a product, such as a drug, condiment or vitamin, encapsulated within biological capsules provided by microorganisms, such as yeast. The disclosure of Shank teaches microencapsulation of substances to provide microcapsules. Microencapsulation is a technique for enclosing substances in individual cells. The encapsulated substances in Shank are fat-soluble, i.e., liquids, such as pigments. The appearance of the products after microencapsulation is that of a grain or a powder.

The present invention is distinguishable as relating to the technique of forming films of a coating agent comprising yeast cell wall fractions onto a substance. Film formation is submitted to be essentially different from encapsulation as an artisan would readily appreciate.

Further, the substances to be coated in the present invention are solids and it does not matter whether the substances are fat-soluble or water-soluble. The appearance of Applicants' coated material is a fine particle, a granule, a tablet, or the like. Therefore, the coating agent, coated material, and coating film of the present invention are distinguishable and essentially different from the substances employed and the coating result obtained by Shank.

**The rejection of claims 15-37 under 35 U.S.C. §103 as being unpatentably obvious over Provonchee et al. in view of Jamas et al. (US 6,020,324) is respectfully traversed.** The Examiner acknowledges that Provonchee et al. do not disclose a plasticizer for which reason the Examiner relies on Jamas et al.

Applicants do not agree that the combined disclosures of Provonchee et al. and Jamas et al. set out a *prima facie* case of obviousness against new claims 15-37 (1) because Applicants traverse the combination of Provonchee et al. and James et al. and (2) because - even if combined - the combined disclosures do not meet Applicants' claims.

Jamas et al. relates to a composition and method utilizing yeast glucan **as a dietary additive**. Jamas et al. relates to compositions useful for treatment of dietary disorders. Though Jamas et al. refer to coating material and plasticizer, these are mentioned only in the context of making tablets out of glucan compositions for oral administration. Jamas et al. do not suggest that glucan **is** a coating agent.

The present invention is distinguishable as teaching supplemental materials to protect useful substances by coating a film thereon. Applicants are **not** seeking to provide compositions

useful for treatment of dietary disorders as is James et al. which employs glucan as an active ingredient for reduction of the level of serum cholestetrol, for example.

Furthermore, James et al. does not teach or suggest dissolution control provided by a coating provided on a coated material unlike the present invention where there is a concrete disclosure about designing dissolution control by additives, such as agar or glycerol.

Applicants' respectfully submit that Jamas et al. has nothing to do with the present invention and respectfully traverse the combination of Provonchee et al. and Jamas et al. as finding no suggestion in either reference.

Moreover, the composition of the product of the present invention is different from the disclosed composition of Provonchee et al. and has nothing to do with making tablets by adding plasticizer as taught by Jamas et al. Thus, if, for the sake of argument, the combination of the disclosures of Provonchee et al. and James et al. is made, Applicants submit that the coating agent, coated material, and coating film of the present invention would not result Applicants coating agent, coated material, and coating film are submitted to be distinguishable and essentially different from those possible from any such combination for the reasons given in the foregoing.

**The rejection of claims 15-37 under 35 U.S.C. §103 as being unpatentably obvious over Shank (US 4,001,480) in view of Jamas et al. (US 6,020,324) is respectfully traversed.** The Examiner acknowledges that Shank does not disclose a plasticizer for which reason the Examiner relies on Jamas et al.

Applicants do not agree that the combined disclosures of Shank and Jamas et al. set out a *prima facie* case of obviousness against new claims 15-37 (1) because Applicants traverse the combination of Shank and James et al. and (2) because - even if combined - the combined disclosures do not meet Applicants' claims.

As discussed in the foregoing, Jamas et al. relates to a composition and method utilizing yeast glucan **as a dietary additive**. Jamas et al. relates to compositions useful for treatment of dietary disorders. Though Jamas et al. refer to coating material and plasticizer, these are mentioned only in the context of making tablets out of glucan compositions for oral administration. Jamas et al. do not suggest that glucan **is** a coating agent.

The present invention is distinguishable as teaching supplemental materials to protect useful substances by coating a film thereon. Applicants are **not** seeking to provide compositions useful for treatment of dietary disorders as is James et al. which employs glucan as an active ingredient for reduction of the level of serum cholestetrol, for example.

Furthermore, James et al. does not teach or suggest dissolution control provided by a coating provided on a coated material unlike the present invention where there is a concrete disclosure about designing dissolution control by additives, such as agar or glycerol.

Applicants' respectfully submit that Jamas et al. has nothing to do with the present invention and respectfully traverse the combination of Shank and Jamas et al. as finding no suggestion in either reference.

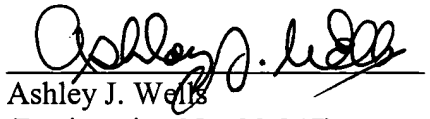
Moreover, the composition of the product of the present invention is different from the disclosed composition of Shank and has nothing to do with making tablets by adding plasticizer as taught by Jamas et al. That is, if an artisan were to change the composition and the methods

disclosed by Shank to a composition including plasticizer and a method to make tablets as disclosed by Jamas et al., the product of Shank would be presumed to be only a substance consisting of a group of microcapsules. Thus, if, for the sake of argument, the combination of the disclosures of Shank and James et al. is made, Applicants submit that the coating agent, coated material, and coating film of the present invention would not result Applicants coating agent, coated material, and coating film are submitted to be distinguishable and essentially different from those possible from any such combination for the reasons given in the foregoing.

In view of the foregoing amendments and remarks, it is requested that the rejections of record be reconsidered and withdrawn, that claims 15-39 be allowed, and that the Application be found to be in allowable condition.

Should the Examiner not find the Application to be in allowable condition or believe that a conference would be of value in expediting the prosecution of the Application, Applicants request that the Examiner telephone undersigned Counsel to discuss the case and afford Applicants an opportunity to submit any Supplemental Amendment that might advance prosecution and place the Application in allowable condition.

Respectfully submitted,



Ashley J. Wells
(Registration No. 29,847)

VENABLE
Post Office Box 34385
Washington, DC 20043-9998
Telephone: (202) 962-4800
Direct dial: 202-962-4084
Telefax : (202) 962-8300

DC2-DOCS1-317817

# MARKED-UP VERSION OF CLAIMS 15-37:

15. (Once amended) A coating agent which is a plastic fluid, comprising:

yeast cell wall fractions, as a primary constituent, consisting of cell residue of enzyme-treated yeast containing at least a reduced amount of internal soluble cell constituents,

wherein the coating agent has properties of a plastic fluid and provides a pre-selected dissolution time in a solvent in use.

16. (Maintained) The coating agent according to claim 15, further comprising a plasticizer.

17. (Once amended) A coated material, comprising:

a solid material to be coated; and

a coating comprised of the coating agent according to claim 15 provided on the solid material,

wherein the coating agent is applied in a thickness effective to provide the pre-selected dissolution time in the solvent.

18. (Once amended) The coated material according to claim 17, wherein the solid material is a granular substance selected from the group consisting of fine particles, granules, and tablets.

19. (Once amended) The coated material according to claim 17 [18], wherein the solid material is a substance selected from the group consisting of food products, food product materials, pharmaceutical preparations, enzymes, microorganisms, seeds, agrochemicals, fertilizers, fragrances, and pigments.

20. (Maintained) A coating film, comprising the coating agent according to claim 15.

21. (Maintained) The coating film according to claim 20, further comprising plasticizer.

22. (Once amended) A coating agent which is a plastic fluid, comprising:

yeast cell wall fractions, as a primary constituent, consisting of cell residue of enzyme-treated and acid-treated yeast containing at least a reduced amount of internal soluble cell constituents,

wherein the coating agent has properties of a plastic fluid and provides a pre-selected dissolution time in a solvent in use, and

wherein the amount of internal soluble cell constituents is reduced to a greater degree than that obtained by enzyme treatment without acid treatment due to the acid treatment having further removed the internal soluble cell constituents.

23. (Maintained) The coating agent according to claim 22, further comprising a plasticizer.

24. (Once amended) A coated material, comprising:

a solid material to be coated; and

a coating comprised of the coating agent according to claim 22 provided on the solid material,

wherein the coating agent is applied in a thickness effective to provide the pre-selected dissolution time in the solvent.

25. (Once amended) The coated material according to claim 24, wherein the solid material is a granular substance selected from the group consisting of fine particles, granules, and tablets.

26. (Once amended) The coated material according to claim 24, wherein the solid material is a substance selected from the group consisting of food products, food product materials, pharmaceutical preparations, enzymes, microorganisms, seeds, agrochemicals, fertilizers, fragrances, and pigments.

27. (Once amended) A coating film, comprising the coating agent according to claim 22.

wherein the coating agent is applied in a thickness effective to provide the pre-selected dissolution time in the solvent.

28. (Maintained) The coating film according to claim 27, further comprising plasticizer.

29. (Once amended) An enteric coating agent which is a plastic fluid, comprising:

yeast cell wall fractions, as a primary constituent, consisting of cell residue of enzyme-treated yeast containing at least a reduced amount of internal soluble cell constituents,

wherein the coating agent is edible, has effective enteric properties, has properties of a plastic fluid, and may be applied to have a thickness effective to provide a preselected dissolution time under enteric conditions.

30. (Maintained) The enteric coating agent according to claim 29, wherein the yeast cell wall fractions are acid-treated yeast cell wall fractions, consisting of cell residue of enzyme-treated- and acidic aqueous solution- treated-yeast containing a reduced amount of internal soluble cell constituents which is reduced to a greater degree than that obtained by enzyme treatment due to the acidic aqueous solution treatment having further removed the internal soluble cell constituents.

31. (Maintained) The enteric coating agent according to claim 30, further comprising plasticizer.

32. (Maintained) The enteric coating agent according to claim 29, further comprising plasticizer.

33. (Once amended) A coated material, comprising:

a solid material to be coated; and

a coating comprised of the enteric coating agent according to claim 29 provided on the solid material,

wherein the coating is edible, has effective enteric properties, and has a thickness effective to provide a preselected dissolution time under enteric conditions.

34. (Once amended) The coated material according to claim 33, wherein the solid material is a granular substance selected from the group consisting of fine particles, granules, and tablets.

35. (Once amended) The coated material according to claim 33, wherein the solid material is selected from the group consisting of food products, food product materials, pharmaceutical preparations, enzymes, microorganisms, seeds, agrochemicals, fertilizers, fragrances, and pigments.

36. (Maintained) A coating film comprising the enteric coating agent according to claim 29, wherein the coating film is edible, has effective enteric properties, and has a thickness effective to provide a preselected dissolution time under enteric conditions.

37. (Maintained) The coating film according to claim 36, further comprising plasticizer.